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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,562	01/13/2006	Sven Bulow	SCH-16447	2024
40854 7590 03/26/2008 RANKIN, HILL, & CLARK LLP 38210 Glenn Avenue WILLOUGHBY, OH 44094-7808				
EXAMINER				
MARTINELL, JAMES				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
03/26/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/564,562

**Applicant(s)**

BULOW, SVEN

**Examiner**

James Martinell

**Art Unit**

1634

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9-12, 26-28, 30-37 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 26-28, 30-37 and 43-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/13/06, 2/6/06 & 6/20/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-12, 26-28, 30-37, and 43-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, incomplete, inaccurate, and incomprehensible.

- (a) The recitation of "nucleic acid replication device" (claims 1(a) and 2(a)) is vague and indefinite because there is no clear definition of the term in the application and there is no clear art-recognized meaning for the term.
- (b) The recitation of "the solid phase" (claim 1(b)) is incomplete because there is no antecedent basis for the phrase.
- (c) The recitation of "that are specific for the particular biomolecules" (claim 1(b)) is vague and indefinite because the meaning of the term is not clear. The meaning of "specific for" within the context of the phrase and claim is unclear. Specificity of binding may be affected by the presence of cross-binding or competing molecules present in the reaction or binding mixture. The instant claim does not mention the presence or absence of such molecules.
- (d) The recitation of "the particular biomolecules" (claim 1(b)) is incomplete because there is no antecedent basis for the phrase.
- (e) The recitation of "if called for" (claims 1(c), 1(e), 2(a), 2(d), 3(b), and 3(c)) is vague and indefinite because it is not understood what is meant by the term.
- (f) The recitation of "the non-bound biomolecules/substance complexes" (claim 1(c)) is incomplete because there is no antecedent basis for the phrase.

- (g) The recitation of "are removed" is incomplete because the claim does not recite from what the complexes are removed.
- (h) The recitation of "high molecular weight nucleic acid molecules" (claims 1(d), 1(e), 2(c), 3(c), and 26) is vague, indefinite, and incomplete because the term is a relative one with no given frame of reference.
- (i) The recitation of "mononucleotides" (claims 1(d), 2(c), 3(c), and 26) is inaccurate since mononucleotides cannot be incorporated into growing chains of synthesized nucleic acids. Applicants may have intended to recite "mononucleoside triphosphates" instead. For example, see Lehninger, 1970, *Biochemistry*, Worth Publishers, Inc., New York, page 247, cited here as of interest.
- (j) The recitation of "of various species" (claims 1(d) and 2(c)) is vague and indefinite because the meaning of the term within the context of the claims is not clear.
- (k) The recitation of "the nucleotides" (claim 1(d)) is incomplete because there is no antecedent basis for the term.
- (l) The recitation of "fitted with a detectable marking" (claims 1(d), 2(c), and 26) is vague and indefinite because it is not understood what is meant by the term.
- (m) The recitation of "further with a second substance which complements the first substance into a functional replicating device for high molecular weight nucleic acids" (claim 1(d)) is incomprehensible. The meaning of the phrase is not understood.
- (n) The recitation of "functional replicating device" (claims 1(d) and 26) is vague and indefinite because there is no clear definition of the term in the application and there is no clear art-recognized meaning for the term.

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- (o) The recitation of "high molecular weight nucleic acids" (claims 1(d) 2(c) and 26) is vague, indefinite, and incomplete because the term is a relative one with no given frame of reference.
- (p) The recitation of "said device" (claims 1(d) and 2(c)) is vague and indefinite because the phrase has more than one possible antecedent.
- (q) The recitation of "under integration of marked mononucleotides generating replicas of the high molecular weight nucleic acid molecules" (claim 1(d)) is incomprehensible. The meaning of the phrase is not understood.
- (r) The recitation of "mononucleotides that do not dissociate off it" (claim 1(d)) is incomprehensible. The meaning of the phrase is not understood.
- (s) The recitation of "dissociate off it" (claims 1(d)) 2(c), and 26) is incomplete because the antecedent for "it" is not clear or understood.
- (t) The recitation of "removing by washing" (claims 1(e), 2(a), and 2(d)) is vague and indefinite because it is not clear from what the material is being removed.
- (u) The recitation of "the dissolved high molecular weight nucleic acid molecules and mononucleotides" (claim 1(e)) is incomplete because there is no antecedent basis for the phrase.
- (v) The recitation of "the marked replicas" (claims 1(f) and 2(e)) is incomplete because there is no antecedent basis for the phrase.
- (w) The recitation of "determining the biomolecules to be detected" (claims 1(f) and 2(e)) is vague and indefinite because the meaning of the phrase is not understood within the context of the claims.
- (x) The recitation of "connecting complexes" (claim 2(a)) is vague and indefinite because there is no clear definition of the term in the application and there is no clear art-recognized meaning for the term.

- (y) The recitation of "specific to" (claim 2(a)) is vague and indefinite because there is no clear definition of the term in the application and there is no clear art-recognized meaning for the term. Specificity of binding may be affected by the presence of cross-binding or competing molecules present in the reaction or binding mixture. The instant claim does not mention the presence or absence of such molecules.
- (z) The recitation of "the particular biomolecules" (claim 2(a)) is incomplete because there is no antecedent basis for the phrase.
- (aa) The recitation of "the non-bound connection complexes" (claim 2(a)) is incomplete because there is no antecedent basis for the phrase.
- (bb) The recitation of "a second substance that complements the first substance coupled to the biomolecules into a functional, replicating device for high molecular weight nucleic acids" (claim 2(c)) is incomprehensible. The meaning of the phrase is not understood.
- (cc) The recitation of "functional, replicating device" (claim 2(c)) is vague and indefinite because there is no clear definition of the term in the application and there is no clear art-recognized meaning for the term.
- (dd) The recitation of "under integration of marked mononucleotides replicas of the high molecular weight nucleic acid molecules" (claim 2(c)) is incomprehensible. The meaning of the phrase is not understood.
- (ee) The recitation of "high molecular weight nucleic acids which do not dissociate off it" (claim 2(c)) is incomprehensible. The meaning of the phrase is not understood.
- (ff) The recitation of "the dissolved nucleic acid molecules and mononucleotides" (claim 2(d)) is incomplete because there is no antecedent basis for the phrase.

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- (gg) The recitation of "the connection complexes" (claims 3(a) and 7) is incomplete because there is no antecedent basis for the phrase.
- (hh) The recitation of "specific binding molecules" (claim 3(a)) is vague and indefinite because the meaning of "specific binding" is vague and indefinite because the meaning of the term is not clear. The meaning of "specific binding" within the context of the phrase and claim is unclear. Specificity of binding may be affected by the presence of cross-binding or competing molecules present in the reaction or binding mixture. The instant claims do not mention the presence or absence of such molecules.
- (ii) The recitation of "the dissolved high molecular weight nucleic acid molecules and mononucleotides" (claim 3(c)) is incomplete because there is no antecedent basis for the phrase.
- (jj) The recitation of "the connection complexes" (claim 5) is incomplete because there is no antecedent basis for the phrase.
- (kk) The recitation of "linker systems" (claim 6) is vague and indefinite because the term is not clearly defined in the applicant and there is no clear art-recognized meaning for the term.
- (ll) The recitation of "linker system" (claim 7 and 28) is vague and indefinite because the term is not clearly defined in the applicant and there is no clear art-recognized meaning for the term.
- (mm) The recitation of "the remaining, required sub-units of a DNA polymerase III" (claims 9, 34, and 44) is vague, indefinite, and incomplete because the claims do not make clear for what purpose the sub-units are required.
- (nn) The recitation of "where called for" (claims 10 and 45) is vague and indefinite because the meaning of the term is not clear.

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- (oo) The recitation of "further required sub-units of a DNA polymerase III" (claims 9, 34, and 44) is vague, indefinite, and incomplete because the claims do not make clear for what purpose the sub-units are required.
- (pp) The recitation of "another DNA polymerase" (claims 11, 12, 36, 37, 46, and 47) is vague and indefinite because the meaning of "another" in the phrase is not clear.
- (qq) The recitation of "nucleic acid replicating device" (claim 26) is vague and indefinite because there is no clear definition of the term in the application and there is no clear art-recognized meaning for the term.
- (rr) The recitation of "mononucleotides of different species" (claim 26) is vague and indefinite because the meaning of "different species" is not defined in the application and has no clear art-recognized meaning.
- (ss) The recitation of "also with a second substance that complements the first substance into a functional replicating device for high molecular weight nucleic acids" (claim 26) is incomprehensible. The meaning of the phrase is not understood.
- (tt) The recitation of "while integrating marked mononucleotides, does generate replicas of the high molecular weight nucleic acid molecules that do not dissociate off it" (claim 26) is incomprehensible. The meaning of the phrase is not understood.
- (uu) The recitation of "allowing to bind the molecules to be bound" (claim 28) is vague and indefinite because the meaning of the phrase is not understood within the context of the claim.
- (vv) The recitation of "specifically binding" (claims 30 and 32) is vague and indefinite because the meaning of the term is not clear. The meaning of "specifically binding" within the context of the phrase and claims is unclear.



Specificity of binding may be affected by the presence of cross-binding or competing molecules present in the reaction or binding mixture. The instant claims do not mention the presence or absence of such molecules.

- (ww) The recitation of "able to specifically binding a biomolecule" (claim 30) is vague and indefinite because the meaning of the term is not clear. The meaning of "specifically binding" within the context of the phrase and claim is unclear. Specificity of binding may be affected by the presence of cross-binding or competing molecules present in the reaction or binding mixture. The instant claim does not mention the presence or absence of such molecules.
- (xx) The recitation of "other specifically binding molecules" (claim 32) is vague and indefinite because the meaning of the term is not clear. The meaning of "specifically binding" within the context of the phrase and claim is unclear. Specificity of binding may be affected by the presence of cross-binding or competing molecules present in the reaction or binding mixture. The instant claim does not mention the presence or absence of such molecules.
- (yy) Claim 43 is vague and indefinite because it is an improper hybrid claim. The claim is a product claim that depends from a method claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 26-33, and 43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by either one of Sano et al U.S. Patent No. 5,665,539 or Sano et al (Science 258: 120 (1992)). Each of the references teaches a method for detecting biomolecules by linking antibodies to DNA molecules, binding

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the antibodies to their respective immobilized antigens, and then detecting the bound antibody-DNA complexes by amplifying the DNAs linked to the antibodies with necessary washing steps to remove unbound materials from the immobilized complexes. For example, see '539, column 10, line 40 through column 12, line 43 and Science 258: 120 (1992) at notes 7-14 on page 122. The methods taught in each of the references contain all of the steps, features, and limitations of the instant claims. Likewise, the marker of claim 43 is anticipated by each of the references since each of the references utilizes markers that meet all of the limitations of claim 43.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

#### **OFFICIAL FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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/James Martinell/  
Primary Examiner  
Art Unit 1634